

REMARKS

1. Formal Matters

a. Status of the Claims

Claims 1-16 are pending in this application. Claims 1-16 are hereby canceled without prejudice to pursuing these claims in a continuing application. Claims 17-36 are new. Upon entry of these amendments, claims 17-36 are pending and under active consideration. Applicants respectfully request entry of the amendments and remarks made herein into the file history of the present application.

b. Amendments to the Claims

New claim 17 recites a nucleic acid consisting of 18 to 120 nucleotides, support for which may be found throughout the application including claims 1-3 and paragraph 0015 of the application as originally filed. New claim 17 also recites that the sequence of the nucleic acid may comprise at least 18 consecutive nucleotides of SEQ ID NO: 48, support for which may be found at Table 2, lines 1116-1120 and paragraph 50905 of the application as originally filed.

Claim 17 is also amended to recite that the nucleic acid may be an RNA equivalent of (a), support for which may be found in the application as originally filed including at paragraph 50906 and claim 1 as originally filed.

Claim 17 is also amended to recite that the nucleic acid may be: a sequence at least 64/84 identical to (a) or (b), support for which may be found at Table 2, lines 1116-1120 and paragraph 26993 of the application as originally filed. SEQ ID NO: 48 forms a hairpin, as shown at Table 2, lines 1116-1120 of the application as originally filed. SEQ ID NO: 48 is 84 nucleotides in length. Within the predicted hairpin formed by SEQ ID NO: 48, 64 complementary nucleotides are paired.

Claim 17 is also amended to recite that the nucleic acid may be: the complement of any one of (a)-(c), support for which may be found at claim 1 and paragraph 50906 of the application as originally filed.

New claim 18 recites the nucleic acid of claim 17, wherein the at least 18 nucleotides comprises the sequence of SEQ ID NO: 354, support for which can be found at Table 2, lines 1116-1120 and paragraph 50907 of the application as originally filed.

New claim 19 recites a nucleic acid of claim 17, wherein the nucleic acid consists of 18 to 24 nucleotides, support for which can be found at claims 1-3 as originally filed.

New claim 20 recites a nucleic acid with a sequence consisting of (a) SEQ ID NO: 48 (b) an RNA equivalent of (a); (c) a sequence at least 64/84 identical to (a) or (b); or (d) the complement of any one of (a)-(c), support for which may be found as described above for new claim 17.

New claim 21 recites a nucleic acid of claim 20, wherein the at least 18 nucleotides comprises the sequence of SEQ ID NO: 354, support for which can be found as described for new claim 18.

New claim 22 recites a nucleic acid of claim 20, wherein the nucleic acid consists of 18 to 24 nucleotides, support for which can be found as described for new claim 19.

New claim 23 recites a nucleic acid of claim 18, wherein the nucleic acid is an RNA, support for which can be found at claim 1 and paragraph 50906 of the application as originally filed.

New claim 24 recites a nucleic acid of claim 21 wherein the nucleic acid is an RNA, support for which can be found at claim 1 and paragraph 50906 of the application as originally filed.

New claim 25 recites a nucleic acid of claim 23, wherein the nucleic acid is capable of modulating expression of a target gene, support for which can be found at claim 3 and paragraph 50902 of the application as originally filed.

New claim 26 recites a nucleic acid of claim 24, wherein the nucleic acid is capable of modulating expression of a target gene, support for which can be found at claim 3 and paragraph 50902 of the application as originally filed.

New claim 27 recites a nucleic acid of claim 25, wherein the nucleic acid is at least 14/30 complementary to a binding site sequence of 18 to 24 nucleotides of a target gene, support for which may be found at Table 4, lines 110852-111681, which show that among all listed target binding sites of the nucleotide represented by SEQ ID NO: 354, the sequence of which is included in the sequence of SEQ ID NO: 48, at the lowest level of complementarity a target binding site of 30 nucleotides has 14 nucleotides complementary to the sequence of SEQ ID NO: 354. New claim 27 also recites that the binding site sequence is located in an untranslated

region of RNA encoded by the target gene, support for which can be found at paragraph 0022 of the application as originally filed.

New claim 28 recites a nucleic acid of claim 26, wherein the nucleic acid is at least 14/30 complementary to a binding site sequence of 18 to 24 nucleotides of a target gene and wherein the binding site sequence is located in an untranslated region of RNA encoded by the target gene, support for which can be found as described for new claim 27.

New claim 29 recites a vector comprising an insert, wherein an insert consists of the nucleic acid of claim 17, support for which can be found at paragraph 0024 of the application as filed.

New claim 30 recites a vector comprising an insert, wherein an insert consists of the nucleic acid of claim 20, support for which can be found at paragraph 0024 of the application as filed.

New claim 31 recites a probe comprising an insert, wherein an insert consists of the nucleic acid of claim 17, support for which can be found at paragraph 0028 of the application as originally filed.

New claim 32 recites a probe comprising an insert, wherein an insert consists of the nucleic acid of claim 20, support for which can be found at paragraph 0028 of the application as originally filed.

New claim 33 recites a gene expression inhibition system comprising the vector of claim 29 and a means for inserting said vector into a cell, support for which can be found at paragraph 0027 of the application as originally filed.

New claim 34 recites a gene expression inhibition system comprising the vector of claim 30 and a means for inserting said vector into a cell, support for which can be found at paragraph 0027 of the application as originally filed.

New claim 35 recites a gene expression detection system comprising the probe of claim 31 and a gene expression detector functional to selectively detect expression of at least one gene, support for which can be found at paragraph 0030 of the application as originally filed.

New claim 36 recites a gene expression detection system comprising the probe of claim 32 and a gene expression detector functional to selectively detect expression of at least one gene, support for which can be found at paragraph 0030 of the application as originally filed.

c. Amendments to the Specification

At page 2 of the Office Action, the Examiner alleges that Figures 12A, 13A, 14A and paragraphs 0201, 0202, 0220 do not comply with sequence rules. Applicant respectfully submits that the objection to the indicated Figures is in error, because Figures 12A, 13A, and 14A do not disclose sequences. Applicant believes that Examiner may have intended to object to Figures 23B and 24A, which disclose sequences.

Paragraphs 0201-0202 are amended to assign SEQ ID NOS: 20201-20209 to the listed sequences in compliance with 37 C.F.R. §§ 1.821-1.825. Paragraphs 0201-0202 are also amended to correct typographical errors.

Paragraph 0206 is amended to assign SEQ ID NOS: 20190-20199 and 20216 to the listed MIRs, GAMS, and controls with sequences represented in Fig. 23B in compliance with 37 C.F.R. §§ 1.821-1.825.

Paragraph 0211 is amended to assign SEQ ID NO: 20200 to the sequence shown in Fig. 24A in compliance with 37 C.F.R. §§ 1.821-1.825.

Paragraph 0220 is amended to assign SEQ ID NOS: 20210-20215 in compliance with 37 C.F.R. §§ 1.821-1.825.

d. Election/Restrictions

At pages 3-6 of the Office Action, the Examiner requires restriction to one of the following inventions under 35 U.S.C. § 121:

- I. Claims 1-10, 13, 14, and 16, drawn to a bioinformatically detectable novel gene, a vector comprising said novel gene, a probe comprising said novel gene, and a vector inserter comprising said probe and a gene expression detector.
- II. Claims 11 and 12, drawn to a method of selectively inhibiting translation of a least one gene.
- III. Claim 15, drawn to a method of selectively detecting gene expression of at least one gene.

Applicant elects without traverse Group I, which now is considered claims 16-36, drawn to an isolated nucleic acid, a vector comprising the nucleic acid, a probe comprising the nucleic acid, a gene expression inhibition system comprising the vector and a means for inserting the vector into a cell, and a gene expression detection system comprising the probe and a gene expression detector functional to selectively detect expression of at least one gene.

e. Sequence Election Requirement for All Groups

At page 6 of the Office Action, the Examiner requires election of a single nucleic acid sequence for the elected Group under 35 U.S.C. § 121. Applicant elects with traverse nucleic acids related to SEQ ID NO: 48.

The Examiner is permitted under 35 U.S.C. § 121 to issue a restriction requirement between independent and distinct inventions. However, the Director has partially waived the requirements of 37 C.F.R. § 1.141 *et seq.* to permit a reasonable number of nucleotide sequences to be claimed in a single application. *See Examination of Patent Applications Containing Nucleotide Sequence*, 1192 O.G. 68 (November 19, 1996). It has been determined that normally ten sequences constitute a reasonable number for examination purposes absent an exceptional case. *See MPEP 803.04.*

The Examiner has failed to demonstrate that the claimed sequences are an exceptional case necessitating that the number of sequences to be selected be less than ten. Applicant respectfully submits that the Examiner is impermissibly disregarding the waiver of 37 C.F.R. § 1.141 *et seq.* Accordingly, Applicant respectfully requests reconsideration of the restriction requirement and the opportunity to elect up to ten sequences for further prosecution.

f. Species Election Regarding Target Genes in Group I

At page 7 of the Office Action, the Examiner requires election of a single target gene under 35 U.S.C. § 121. Applicant elects without traverse target gene BIKE which has the sequence of SEQ ID NO: 2961. Claims 17-36 encompass the elected target gene.

2. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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